K100897

Summary of Safety and Effectiveness
LEGION Porous + HA Tibial Baseplates
Smith & Nephew, Inc.

Contact Person and Address
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Date of Summary: April 14, 2010

MAY 13 2010

Name of Device: Legion Porous + HA Tibial Baseplate
Common Name: Total Knee Prosthesis
Device Classification Name and Reference: 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous coated uncemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87 MBH

Device Description
Subject of this premarket notification is a review of changes to the Profix Porous Tibial Baseplates (previously cleared for market via premarket notification K030623) to result in the Legion Porous + HA Tibial Baseplates. The subject devices are uncemented tibial baseplates manufactured from Ti-6Al-4V material and feature a porous coating of CP Ti beads and an HA coating. The devices will be available in left and right configurations in sizes 2 through 8.

When compared to the predicate Profix Porous Tibial Baseplates, the Legion Porous + HA Tibial Baseplates have been modified as follows:

- Utilization of the Genesis II style periphery, profile, and locking detail
- Addition of HA coating
- Increase in thickness of baseplate

Intended Use
Total knee components are indicated for:

1. Rheumatoid arthritis
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity levels are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. The posterior-stabilized knee system is designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Legion Porous + HA Tibial Baseplates are indicated for use without bone cement, and are single use devices.

Performance Data

Design verification testing has been performed based on requirements outlined in FDA's *Class 2 Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and Staff*, dated January 16, 2003 and *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components* dated May 1, 1995. A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The Legion Porous + HA Tibial Baseplates are substantially equivalent to previously cleared devices listed below. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate knee systems.

Table 1: Predicate knee systems

Description	510(k)	Clearance Date
Profix Total Knee System	K030623	5/22/03
Genesis II Porous + HA Knee System	K032683	10/15/03

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the Legion Porous + HA Tibial Baseplates. Based on the similarities to the predicate devices and a review of the testing, the devices are substantially equivalent to knee components currently marketed under K030623 and K032683.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Orthopaedic Division
Ms. Megan Bevill
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1450 E. Brooks Road
Memphis, Tennessee 38116

MAY 13 2010

Re: K100897
Trade/Device Name: Legion Porous + HA Tibial Baseplates
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: April 14, 2010
Received: April 15, 2010

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Legion Porous + HA Tibial Baseplate

Total knee components are indicated for:

1. Rheumatoid arthritis
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100897